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EXAMINER	
FRENEL, VANEL	
ART UNIT	PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/943,193

Applicant(s)

RIFF ET AL.

Examiner

Vanel Frenel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-21,32-47 and 66-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21,32-47 and 66-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Notice to Applicant***

**1.     *This communication is in response to the application filed August 2001.***

***Claims 1-21, 32-47 and 66-74 are pending.***

***Claim Rejections - 35 USC § 103***

2.     The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3.     Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al (6,264,614) in view of Sato et al (5,911,687).

(A)    As per claim 1, Albert discloses an internet-based method for a paid service to maintain data connectivity of a remote medical device-configured patient to a database network and to enable medical device data exchange and processing (Col.1, lines 9-67), comprising the steps of :

receiving in a substantially continuous manner at a database network site first data inputs uniquely representative of sensed physiologic information from a specific medical device configuration of a patient using said medical device configuration (Col.2, lines 9-43);

enabling the database network site to communicate with at least one web enabled web-site and to receive web-site originated signals requesting access to

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representations of said first data inputs from said database (Col.5, lines 20-67). Albert does not explicitly disclose monitoring data packages to determine revenue for the service.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests monitoring data packages to determine revenue for the service (Col.2, lines 7-63; Col.6, lines 11-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Albert with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient. Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

(B) As per claim 2, Sato discloses the service method further including the step of providing said web-site and configuring said web-site with a user interface which includes a sign-in input to enable access to said database network site (Col.5, lines 1-67 to Col.6, line 67).

(C) As per claim 3, Albert discloses the service method in which the receiving step includes receiving at least one signal carrying information representing sensed physiologic status within the patient from at least one medical device located on or at least partially in the patient's body (Col.5, lines 64-67 to Col.6, line 67).

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(D) As per claim 4, Albert discloses the service method in which the receiving step includes receiving signals carrying information representing actual physiologic phenomenon within the patient as sensed by at least one medical device located on or at least partially in the patient's body (Col.5, lines 64-67 to Col.6, line 67).

(E) As per claim 5, Albert discloses the service method in which the receiving step includes receiving signals carrying information representing actual physiologic phenomenon within the patient as sensed by a plurality of medical devices located on or at least partially in the patient's body (Col.6, lines 1-67).

(F) As per claim 6, Albert discloses the service method in which the enabling step comprises providing a secure sign-in and validating an originator's security-related action prior to allowing access of the originator to the database information (Col.7, lines 11-67 to Col.8, line 47).

(G) As per claim 7, Albert discloses the service method in which the first data inputs provides intermediate information to enable further production of data representations enabling subsequent actions (Col.7, lines 11-67 to Col.8, line 5).

(H) As per claim 8, Albert discloses an internet-based method for a paid service to maintain connection of a remote medical device configured patient to a database

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network and for medical device data exchange and processing (Col.1, lines 9-67)

comprising the steps of

providing a web-site in a web-enabled system, the web-site having a user interface which includes a sign-in input to enable access to a database network site associated

with said web-enabled system (Col.2, lines 16-67; Col.7, lines 4-67 to Col.8, line 47);

receiving in a substantially continuous manner at the database network site first data inputs uniquely representative of sensed physiologic information from a device

configuration of a patient using said medical device

specific medical configuration (Col.7, lines 4-67 to Col.8, line 67);

receiving at the web-site second data inputs requesting access to representations of said first data inputs available at said database (Col.11, lines 4-67 to Col.12, line 41).

Albert does not explicitly disclose enabling the originator of said second data inputs to have access to the database via the secure web site to view representations of said first data inputs.

However, this feature is well known in the art, as evidenced by Sato. In particular, Sato suggests enabling the originator of said second data inputs to have access to the database via the secure web site to view representations of said first data inputs (Col.15, lines 20-67 to Col.16, line 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Albert with the motivation of providing a recipient computer located at a medical facility and connected to communicate with the computer communication network, wherein the recipient

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computer is programmed to receive the data transferred over the computer communication network and to provide a visible representation of the sensed body function or condition to store the data in a searchable base (See Albert, Col.59-67 to Col.3, line 34).

(I) Claims 9-13 recite the underlying process steps of the elements of claims 3-7, respectively. As the various elements of claims 3-7 and have been shown to be either disclosed by or obvious in view of the collective teachings of Albert and Sato, it is readily apparent that the apparatus disclosed by the applied prior art performs the recited underlying functions. As such, the limitations recited in claims 9-13 are rejected for the same reasons given above for method claims 3-7, and incorporated herein.

(J) As per claim 14, Albert discloses an internet-based method for a paid service to maintain data connectivity of a remote medical device-configured patient to a database network and to enable medical device data exchange and processing (Col.1, lines 9-67), comprising the steps of receiving in a substantially continuous manner at a database network site first data inputs uniquely representative of sensed physiologic information from a specific medical device configuration of a patient using said medical device configuration (Col.2, lines 9-43); initiating processing of said first data inputs to produce user accessible signals which represent the first data inputs in a user accessible format to enable action based on observations of the user accessible signals (Col.5, lines 20-67).

Albert does not explicitly disclose enabling the database network site to communicate with at least one web enabled web-site and to receive web-site originated signals requesting access to representations of said first data inputs from said database.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests enabling the database network site to communicate with at least one web enabled web-site and to receive web-site originated signals requesting access to representations of said first data inputs from said database (Col.15, lines 20-67 to Col.16, line 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Albert with the motivation of providing a recipient computer located at a medical facility and connected to communicate with the computer communication network, wherein the recipient computer is programmed to receive the data transferred over the computer communication network and to provide a visible representation of the sensed body function or condition to store the data in a searchable base (See Albert, Col.59-67 to Col.3, line 34).

(K) As per claim 15, Albert discloses the service method in which the step of initiating processing includes initiating analysis of the first data inputs to determine whether any sensed physiologic activity is abnormal (Col.6, lines 10-44).

(L) As per claim 16, Albert discloses the service method in which the step of initiating processing includes initiating analysis of the first data inputs to determine actual values for any sensed physiologic activity (Col.5, lines 46-67 to Col.6, line 67).



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(M) As per claim 17, Albert discloses the service method in which the step of initiating processing includes initiating analysis of the first data inputs to determine whether any sensed physiologic activity is indicative of a demonstrable or likely pattern of physiological activity (Col.5, lines 46-67 to Col.6, line 44).

(N) As per claim 18, Albert discloses an internet-based method for a paid service to maintain data connectivity of a remote medical device-configured patient to a database network and to enable rapid medical device data exchange and processing of certain conditions (Col.5, lines 20-67) comprising the steps of:

receiving in a substantially continuous manner at a database network site first data inputs uniquely representative of sensed physiologic information from a specific medical device configuration of a patient using said medical device configuration (Col.2, lines 9-43). Albert does not explicitly disclose enabling the database network site to communicate with at least one web-enabled web-site to automatically deliver representations of said first data inputs from said database when certain conditions are met.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests enabling the database network site to communicate with at least one web-enabled web-site to automatically deliver representations of said first data inputs from said database when certain conditions are met (Col.15, lines 20-67 to Col.16, line 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Albert with the motivation of providing

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a recipient computer located at a medical facility and connected to communicate with the computer communication network, wherein the recipient computer is programmed to receive the data transferred over the computer communication network and to provide a visible representation of the sensed body function or condition to store the data in a searchable base (See Albert, Col.59-67 to Col.3, line 34).

(O) As per claim 19, Albert discloses the service method in which the step of enabling includes initiating automatic software analysis of the first data inputs to determine whether any sensed physiologic activity is abnormal (Col.6, lines 1-67 to Col.7, line 65).

(P) As per claim 20, Albert discloses the service method in which the step of enabling includes initiating automatic software analysis of the first data inputs to determine actual values for any sensed physiologic activity (Col.6, lines 1-67 to Col.7, line 65).

(Q) As per claim 21, Albert discloses the service method in which the step of enabling includes initiating automatic software analysis of the first data inputs to determine whether any sensed physiologic activity is indicative of a demonstrable or likely pattern of physiological activity (Col.6, lines 1-67 to Col.7, line 65).

4. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al (6,264,614) in view Krichen et al (6,250,309).

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(R) As per claim 32, Albert discloses a computer implemented method for improved data management in the healthcare industry by increasing patient engagement with recommended healthcare delivery modalities (Col.1, lines 13-67), comprising the steps of;

b. configuring a patient accessible electronic interface to receive signals representative of sensed high relevance biological data of the patient (Col.1, lines 13-67 to Col.2, line 67);

c. providing selectively programmable computer implemented rapid interpretations of the sensed high relevance biologic data and, when indicated, electronically sharing with the healthcare professional the details of the sensed high relevance biological data without resort to personal contact or face to face meeting between the healthcare professional and the patient (Col.1, lines 13-67 to Col.2, line 67); and

d. providing information flow paths for the healthcare professional to further contribute to the knowledge database and patient engagement by offering the patient and a patient's designated advocate direct information about the high relevance biologic data thereby actively engaging the patient in a highly content rich yet efficient manner (Col.2, lines 44-67 to Col.3, line 67). Albert does not explicitly disclose providing an implanted medical device configured for automatic sensing of high relevance biologic data of the patient and transmitting that data, or portions thereof, to an information parser of the healthcare professional.

However, this known in the art, as evidenced by Krichen . In particular, Krichen suggests an implanted medical device which stimulating body organs and tissue to evoke a response for enhancing a body function or to control pain, and drug delivery devices for

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releasing a drug bolus at a selected site (See Krichen Col.3, lines 49-67 to Col.4, line 67 ; Col.11, lines 31-67 to Col.12, line 67 ).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Krichen within the system of Albert with the motivation of providing the ability to transfer the desired information about the implantable medical device over most communication modules to the remote location via an internet connection such as a local area network connection, a telephone line connection, or a radio frequency connection (See Krichen Col.2, lines 65-67 to Col.3, line 3).

5. Claims 33- 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al (6,264,614) in view of Brown (6,101,478).

(S) As per claim 33, Albert discloses a computer implemented internet-based method for an improved connect and monitoring service to rapidly connect remote persons to a database network for medical device data exchange and analysis (Col.5, lines 20-67) said method being characterized in that it comprises the steps of

providing a web-site having a user interface wherein the user interface includes a secure sign-in input to access a database network site (Col.8, lines 6-67);

receiving at the web-site automatic inputs associated with a specific medical device and user of the device (Col.8, lines 6-67 to Col.9, line 48); and

enabling the user to access the database via the web-site to use the service for real time monitoring of high relevance physiologic data mined from all monitored data of the user (Col.3,

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lines 1-60; Col.7, lines 4-67 to Col.8, line 53). Albert does not explicitly disclose automatically confirming the identity of the medical device and the user.

However, this feature is known in the art, as evidenced by Brown. In particular, Brown suggests automatically confirming the identity of the medical device and the user (See Brown , Col.3, lines 2-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Brown within the system of Albert with the motivation of providing a data which contains information about an individual's identity. The remotely programmable apparatus includes a data card reader in which the data card can be placed and read. A personal identification number (PIN) can also be used in conjunction with the data card in order to confirm an individual's identity (See Brown, Col.4, lines 27-35).

(T) As per claim 34, Albert discloses the method wherein said web-site further includes a proxy right access scheme to provide privileged access to a user's data by friends or family as programmed (Col.10, lines 37-59).

(U) As per claim 35, Albert discloses a computer implemented internet-based method for improved user compliance within a medical patient management system in which the system automatically determines which connection protocols to follow to rapidly connect one or more remote persons to a database network for medical device data exchange and analysis under certain conditions (Abstract, lines 1-18; Col.1, lines 9-67), said method being characterized in that it comprises the steps of

providing a web-site having a user interface wherein the user interface includes a secure sign-in input protocol to access a database network site (Col.8, lines 6-67);

receiving at the web-site automatic inputs associated with a specific medical device and user of the device (Col.8, lines 6-67 to Col.9, line 48); and

performing computer implemented analyses to determine which user groups to rapidly and selectively automatically access the database via the web-site for receipt of high relevance physiologic data mined from all monitored data of the user (Col.3, lines 1-60; Col.7, lines 4-67 to Col.8, line 53). Albert does not explicitly disclose automatically confirming the identity of the medical device and the user.

However, this feature is known in the art, as evidenced by Brown. In particular, Brown suggests automatically confirming the identity of the medical device and the user (See Brown , Col.3, lines 2-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Brown within the system of Albert with the motivation of providing a data which contains information about an individual's identity. The remotely programmable apparatus includes a data card reader in which the data card can be placed and read. A personal identification number (PIN) can also be used in conjunction with the data card in order to confirm an individual's identity (See Brown, Col.4, lines 27-35).

(V) As per claim 36, Brown discloses the computer implemented internet-based method for improved user compliance further comprising:

alerting a select group of medical providers to an event using an event service (Col.1, lines 18-67);

and

enabling the select group of medical providers to execute secure access to the device user's database in a single sign-on action per user in the group (Col.11, lines 18-67).

(W) As per claim 37, Brown discloses the method wherein said single sign-on action includes authentication to a foreign web-site that is passed over to access the secure device user's database (Col.17, lines 1-67 to Col.18, line 54).

(X) As per claim 38, Albert discloses the method further characterized by computer implemented automatic formatting of automatically processed high relevance data mined from all detected data, and electronically pushing the formatted data to an electronic display of at least one member of a group of medical providers whereby at least one of the group of medical providers selectively provides commentary and then directs a data transmission back via the web site to the user of the medical device, to a designated advocate of the user of the medical device, and, optionally, to another member of a medical providers group (Col.3, lines 48-67 to Col.4, lines 53).

6. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al (6,264,614) in view of Brown (6,168,563).

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(Y) As per claim 39, Albert discloses a computer implemented patient management network configured for implementing the method of automatically determining which connection protocols to follow to rapidly connect one or more remote persons to a database network for medical device data exchange and analysis under certain conditions (Abstract, lines 1-18; Col.1, lines 9-67), said network being characterized in that it comprises:

a web site having a user interface wherein the user interface includes a secure sign-in input protocol to access a database network site (Col.8, lines 6-67);

sensing and signal components for providing automatic inputs to the web site associated with a specific medical device and user of the device (Col.2, lines 17-67; Col.3, lines 35-67 to Col.4, lines 49). Albert does not explicitly disclose processing routines and module for automatically confirming the identity of the medical device and the user; and processing routines and module for performing computer implemented analyses to determine which user groups to rapidly and selectively automatically access the database via the web-site for receipt of high relevance physiologic data mined from all monitored data of the user.

However, these features are known in the art, as evidenced by Brown. In particular, Brown suggest processing routines and module for automatically confirming the identity of the medical device and the user; and processing routines and module for performing computer implemented analyses to determine which user groups to rapidly and selectively automatically access the database via the web-site for receipt of high relevance physiologic data mined from all monitored data of the user (See Brown Col.15, lines 17-67 Col.16, line 67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Brown within the system of Albert with the motivation of



providing one monitor device for producing measurements of a physiological condition of the individual and for transmitting the measurements to the apparatus (See Brown, Col.9, lines 61-67).

7. Claims 40- 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,168,563) in view of Sato et al (5,911,687).

(Z) As per claim 40, Brown discloses a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices (Col.1, lines 20-67 to Col.2, line 21) comprising:

a server hosting medical and physiological data collected from the patient (Col.24, lines 66-67 to Col.25, line 42);

a physician station in data communications with the server (Col.24, lines 27-67 to Col.25, line 42); and

a health care system information network being in a bi-directional communication with the physician station and further having a data communication with the server (Col.24, lines 27-67 to Col.25, line 42);

a disease management organization in bi-directional communications with said health care system information network (Col.1, lines 20-67 to Col.2, line 67; Col.4, lines 16-46). Brown does not explicitly disclose said server including at least one set of database of information concerning the patient wherein the database is structured to assist the disease management organization to manage the patient for a fee.

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However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests server including at least one set of database of information concerning the patient wherein the database is structured to assist the disease management organization to manage the patient for a fee (Col.2, lines 7-63; Col.6, lines 11-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Brown'563 with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient. Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

(AA) As per claim 41, Brown discloses a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices (Col.1, lines 20-67 to Col.2, line 21) comprising:

a server hosting medical and physiological data collected from the patient; a physician station in data communications with the server (Col.24, lines 66-67 to Col.25, line 42); and

a health care system information network being in a bi-directional communication with the physician station and further having a data communication with the server (Col.24, lines 27-67 to Col.25, line 42);

a disease management organization in bi-directional communications with said health care system information network (Col.1, lines 20-67 to Col.2, line 67; Col.4, lines 16-46). Brown

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does not explicitly disclose said server including at least one set of database of information concerning the patient wherein the database is structured to assist the health care system information network to manage the patient or a fee.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests server including at least one set of database of information concerning the patient wherein the database is structured to assist the disease management organization to manage the patient for a fee (Col.2, lines 7-63; Col.6, lines 11-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Brown'563 with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient. Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

(BB) As per claim 42, Brown discloses a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices (Col. 1, lines 20-67 to Col.2, line 21) comprising:

a server hosting medical and physiological data collected from the patient (Col.24, lines 66-67 to Col.25, line 42);

a physician station in data communications with the server (Col.24, lines 66-67 to Col.25, line 42);

a health care system information network being in a bi-directional communication with the physician station and further having a data communication with the server (Col.24, lines 27-67 to Col.25, line 42). Brown does not explicitly disclose said server including at least one set of database of information concerning the patient wherein the database is structured to assist the health care system information network to manage the patient or a fee.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests server including at least one set of database of information concerning the patient wherein the database is structured to assist the health care system information network to manage the patient for a fee (Col.2, lines 7-63; Col.6, lines 11-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Brown'563 with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient. Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

(CC) As per claim 43, Brown discloses a system for implementing a disease management service for a remote chronic patient with an implantable medical device and/or wearable device wherein the service includes multi-users of data and information exchange systems cooperating to provide the service for continuously managing the chronic patient's disease, health care and medical devices (Col.1, lines 20-67 to Col.2, line 21) comprising:

a server hosting medical and physiological data collected from the patient (Col.24, lines 66-67 to Col.25, line 42);

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a physician station in data communications with the server (Col.24, lines 66-67 to Col.25, line 42); and

a disease management organization in bi-directional communications with said server and said physician station (Col.1, lines 20-67 to Col.2, line 67; Col.4, lines 16-46). Brown does not explicitly disclose said server including at least one set of database of information concerning the patient wherein the database is structured to assist the disease management organization to manage the patient for a fee.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests server including at least one set of database of information concerning the patient wherein the database is structured to assist the disease management organization to manage the patient for a fee (Col.2, lines 7-63; Col.6, lines 11-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Brown'563 with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient. Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

(DD) As per claim 44, Brown discloses a data collection and transfer system for implementing a chronic remote patient monitoring service for transmission of very high relevance medical and physiological data from a person having at least one implanted and/or wearable medical device (Col.1, lines 20-67 to Col.2, line 21), the service comprising:

a server hosting high relevance medical and physiological data accessible via a remote monitor in data communications with the server (Col.9, lines 20-67 to Col.10, line 5);

at least one medical device implanted or wearably located on a person being in data communication with the remote monitor (Col.1, lines 20-67).

Brown does not explicitly disclose the server being web-enabled to host and provide multi-directional data collections from various services including said person so that the collected data may be re-transmitted for a fee provided by one or more recipients of the data.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests the server being web-enabled to host and provide multi-directional data collections from various services including said person so that the collected data may be re-transmitted for a fee provided by one or more recipients of the data (Col.2, lines 7-63; Col.6, lines 11-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Brown'563 with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient. Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

(EE) As per claim 45, Albert discloses the service wherein said at least one implanted and/or wearable medical device is in wireless communication with the remote monitor to enable data communications when the person is ambulatory (Col.9, lines 8-20).

(FF) As per claim 46, Sato discloses the service wherein said server includes programmable parameters to bill the person for services rendered (Col.2, lines 1-67 to Col.3, lines 30).

(GG) As per claim 47, Brown discloses a system for implementing a computerized healthcare information service network capable of collecting medical data from various remote locations including a patient with a medical device (Col.1, lines 20-67 to Col.2, line 21), the information service comprising:

- a server hosting medical and physiological data collected from a patient at a remote location, said server being in data communications with a remote monitor that collects highly relevant data from the patient having at least one implanted and/or externally worn medical device (Col.9, lines 20-67 to Col.10, line 5);

- a physician station (Col.15, lines 58-67) ;

- a health care system information network in data communications with the server and the physician station (Col.15, lines 1-57). Brown does not explicitly disclose a billing service for the remote management of the patient's health including a service of the performance of at least one implanted and/or externally worn medical device communicating with the physician station for expert opinion and advising the patient in real time, to provide as to proper procedures to follow for therapy and medical care.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests a billing service for the remote management of the patient's health including a service of the performance of at least one implanted and/or externally worn medical device communicating with the physician station for expert opinion and advising the patient in real

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time, to provide as to proper procedures to follow for therapy and medical care (Col.2, lines 7-63; Col.6, lines 11-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Brown'563 with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient. Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

8. Claims 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,168,563) in view of Sato et al (5,911,687).

(HH) As per claim 66, Brown discloses a network-enabled system for implementing a chronic data management and monitoring service for remote patients and medical devices (Col.1, lines 20-57 to Col.2, line 21) comprising:

a server computer hosting high relevance data transmitted from the remote patients and medical devices (Col.24, lines 27-67 to Col.25, line 42);

a client computer providing access to a plurality of users of the service; and wherein said server computer provides a user interface whereby said plurality of users are authenticated prior to accessing said data (Col.24, lines 27-67 to Col.25, line 57 . Brown does not explicitly disclose

whereby the service is available via one of a secure Internet channels to enable an authenticated user to access data pertaining to a specific patient and/or medical device.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests whereby the service is available via one of a secure Internet channels to enable an



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authenticated user to access data pertaining to a specific patient and/or medical device (See Sato, Abstract, lines 1-22; Col.2, lines 1-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Brown'563 with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient. Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

(II) As per claim 67, Sato discloses the service wherein said service utilizes billing and collection systems consisting of one of computer to computer transactions, monthly statements, direct credit card transfer, micro-payment-systems and business to business collection systems (Col.7, lines 10-30).

9. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al (6,264,614) in view of Brown (6,168,563).

(JJ) As per claim 68, Albert discloses an internet-based information network service for implementing medical data transfer and exchange in a health care system (Abstract, lines 1-18; Col.1, lines 9-67; Col.5, lines 26-67) comprising:

means for collecting medical data from multiple remote sites (Col.1, lines 9-67; Col.6, lines 1-67); and

interface means for accessing said means for collecting by authorized agents (Col.7, lines 39-67 to Col.8, line 67).

Albert does not explicitly disclose wherein said interface means includes controls for authenticating a user for the service and provides selection criteria and display at any one of said multiple remote sites for the user.

However, this feature is known in the art, as evidenced by Brown'563. In particular, Brown'563 suggests wherein said interface means includes controls for authenticating a user for the service and provides selection criteria and display at any one of said multiple remote sites for the user (Col.16, lines 3-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Brown'563 within the system of Albert with the motivation of providing one monitor device for producing measurements of a physiological condition of the individual and for transmitting the measurements to the apparatus (See Brown, Col.9, lines 61-67).

10. Claims 69-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (6,168,563) in view of Sato et al (5,911,687).

(KK) As per claim 69, Brown discloses an information system for generating medical device performance data, in real time, to enhance product performance and adapt businesses methods to provide a continuously improving service to a chronic patient or other information users (Col.3, lines 3-67 to Col.4, line 67; Col.5, line 55), the information system comprising:

a server hosting data transmitted from a remote patient (Col.24, lines 54-67 to Col.25, line 42);

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a plurality of client computers providing access to the server (Col.25, lines 1-67). Brown does not explicitly disclose a medical device manufacturer computer being in data communications with the server wherein device data is managed to provide at least one functional group within a medical device manufacturer with highly relevant information derived from the medical device performance data for use in product or service improvement actions.

However, this feature is known in the art, as evidenced by Sato. In particular, Sato suggests a medical device manufacturer computer being in data communications with the server wherein device data is managed to provide at least one functional group within a medical device manufacturer with highly relevant information derived from the medical device performance data for use in product or service improvement actions (See Sato, Col.5, lines 1-67 to Col.6, line 31).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Brown'563 with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient. Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

(LL) As per claim 70, Sato discloses system in which the functional sub-group is one of research and development, product planning, post market surveillance, and sales and marketing (Col.7, lines 10-65).

(MM) As per claim 71, Sato discloses the system in which the other information users include one of disease management organizations and healthcare management organizations (Col.7, lines 5-65).

(NN) As per claim 72, Brown discloses a system for implementing networked remote patient management services comprising:

a server hosting high relevance patient management data (Col.24, lines 54-67 to Col.25, line 25)for providing chronic monitoring of the remote patients with chronic disease having implantable medical devices and/or wearable devices (Col.3, lines 3-67 to Col.4, line 67; Col.5, line 55)

said server being accessible via client computers wherein said client computers include a web-enabled system, a medical device manufacturer web-site, a physician site, a health care information network site, and a disease management organization (Col.24, lines 27-67 to Col.25, line 67). Brown does not explicitly disclose each of said client computers being in data communications with the server to import specific data on which the patient management services billing schemes, for at least one service, are implemented.

However, this feature is known in the art as evidenced by Sato. In particular, Sato suggests the patient management services billing schemes, for at least one service, are implemented (See Brown, Col.1, lines5-67 to Col.2, line 67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Sato within the system of Brown'563 with the motivation of providing the treatment fee which can be withdrawn automatically from the account of a patient.

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Therefore, the problem of waiting for accounting which is required in a conventional hospital is eliminated (See Sato Col.3, lines 27-30).

11. Claims 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al (6,264,614) in view of Brown (6,101,478).

(OO) As per claim 73, Albert discloses an internet-based method in a web-enabled system for a paid service to connect a remote patient to a database network for medical device data exchange and processing (Col.1, lines 9-67) comprising the steps of

providing a web-site in a web-enabled system, the web-site having a user interface which includes a secure sign-in input to access a database network site associated with said web-enabled system (Col.5, lines 26-67);

automatically receiving at the database network site first data inputs uniquely associated with a specific medical device and patient using said medical device (Col.3, lines 6-67 to Col.4, line 49);

receiving at the web-site second data inputs requesting access to representations of said first data inputs (Col.8, lines 6-67 to Col.9, line 48);

enabling the originator of said second data inputs to have access to the database to view representations of said first data inputs (Col.3, lines 1-60; Col.7, lines 4-67 ; Col.9, line 48).

Albert does not explicitly disclose confirming the identity of the medical device, the patient, and the originator of said second data inputs.

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However, this feature is known in the art, as evidenced by Brown'478. In particular, Brown suggests confirming the identity of the medical device, the patient, and the originator of said second data inputs (See Brown , Col.3, lines 2-67 to Col.4, line 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Brown within the system of Albert with the motivation of providing a data which contains information about an individual's identity. The remotely programmable apparatus includes a data card reader in which the data card can be placed and read. A personal identification number (PIN) can also be used in conjunction with the data card in order to confirm an individual's identity (See Brown, Col.4, lines 27-35).

(PP) As per claim 74, Albert discloses an internet-based method in a web-enabled system for a paid service to connect a remote patient to a database network for medical device data exchange and processing (Col.1, lines 9-67) comprising the steps of

providing a web-site in a web-enabled system, the web-site having a user interface which includes a secure sign-in input to enable access to a database network site associated with said web-enabled system (Col.5, lines 26-67);

periodically receiving at the database network site first data inputs uniquely associated with a specific medical device and patient using said medical device (Col.3, lines 6-67 to Col.4, line 49);

receiving at the web-site second data inputs requesting access to representations of said first data inputs (Col.8, lines 6-67 to Col.9, line 48);

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enabling the originator of said second data inputs to have access to the database via the secure web site to view representations of said first data inputs (Col.3, lines 1-60; Col.7, lines 4-67 ; Col.9, line 48).

Albert does not explicitly disclose confirming the identity of the medical device, the patient, and the originator of said second data inputs.

However, this feature is known in the art, as evidenced by Brown'478. In particular, Brown'478 suggests confirming the identity of the medical device, the patient, and the originator of said second data inputs (See Brown , Col.3, lines 2-67 to Col.4, line 35).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the feature of Brown within the system of Albert with the motivation of providing a data which contains information about an individual's identity. The remotely programmable apparatus includes a data card reader in which the data card can be placed and read. A personal identification number (PIN) can also be used in conjunction with the data card in order to confirm an individual's identity (See Brown, Col.4, lines 27-35).

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches method and system for remotely monitoring multiple medical parameters in an integrated medical monitoring system (6,364,834), system and method for managing patient care (US 2002/0169636) and real time ambulatory patient monitor (5,544,661).

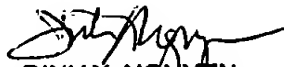
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 703-305-4952. The examiner can normally be reached on 6:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9643. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

V.F  
V.F  
January 13, 2003

  
DINH X. NGUYEN  
PRIMARY EXAMINER